



IFW
3763

Attorney Docket No. WELD 111 DIV IV

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

Ron WAKSMAN et al

Serial No.: 09/468,496

Filed: December 21, 1999

Examiner: M. Desanto

Art Unit: 3763

For: METHOD AND APPARATUS FOR TREATING
A DESIRED AREA IN THE VASCULAR
SYSTEM OF A PATIENT

)
)
) I hereby certify that this correspondence
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) Date: September 23, 2004

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Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97, as revised on February 4, 1992, 1135 OG 23-24, Applicant hereby calls the Examiner's attention to documents listed on the attached form, which documents may be material to the examination of this application. Each of the cited documents is believed to have been cited in one of the parent applications relied upon for priority under 35 USC §120 or a related application. It is not believed that a copy of the references needs to be submitted.

If the Examiner wishes to receive a copy of any of these references, it is respectfully requested that he contact the

undersigned regarding the desired reference and the undersigned will gladly provide the reference.

No inference should be drawn that the attached list sets forth a comprehensive investigation of the prior art, that any or all are pertinent to the invention, or that any apparatus disclosed is equivalent to the subject invention.

The citation of the above-discussed documents is not to be construed as an assertion that more pertinent art could not possibly be in existence. Citation of any document herein is not to be construed as an admission that any subject matter disclosed in the document is necessarily within the inventive field of endeavor, that any disclosure is necessarily prior in time to a particular date which may be relevant to the instant patent application, and/or that any disclosure is otherwise necessarily prior art with respect to the instant invention.

Applicant also respectfully reserves the right to later set forth how the instant invention is distinguished over the disclosure of any document or other art, including the disclosure of those documents discussed herein, that may be cited by the Examiner in rejecting a claim in the instant patent application.

Please charge our Deposit Account No. 50/1039 for any fee due for this IDS.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read "Mark J. Murphy", is written over a horizontal line.

Mark J. Murphy

Registration No.: 34,225

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Sheet 1

of 13

Complete if Known

| | |
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| Application Number | 09/468,496 |
| Filing Date | December 21, 1999 |
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| Examiner Name | M. Desanto |
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U. S. PATENT DOCUMENTS

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|--------------------|-----------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | | US- 1,406,509 | 02-14-1922 | Viol | |
| | | US- 1,753,287 | 04-08-1930 | Failla | |
| | | US- 1,786,373 | 12-23-1930 | Walker | |
| | | US- 2,830,190 | 04-08-1958 | Karp | |
| | | US- 3,145,181 | 08-18-1964 | Courtois, et al. | |
| | | US- 3,154,501 | 10-27-1964 | Hertz | |
| | | US- 3,168,092 | 02-02-1965 | Silverman | |
| | | US- 3,324,847 | 06-13-1967 | Zoumboulis | |
| | | US- 3,351,049 | 11-07-1967 | Lawrence | |
| | | US- 3,532,888 | 10-06-1970 | Masefield, et al. | |
| | | US- 3,589,356 | 06-29-1971 | Silverman | |
| | | US- 3,600,568 | 08-17-1971 | Weyrauch | |
| | | US- 3,632,520 | 01-04-1972 | Garber | |
| | | US- 3,659,107 | 04-25-1972 | Selle, et al. | |
| | | US- 3,669,093 | 06-13-1972 | Sauerwein, et al. | |
| | | US- 3,674,006 | 07-04-1972 | Holmer | |
| | | US- 3,811,426 | 05-21-1974 | Culver, et al. | |
| | | US- 3,872,856 | 03-25-1975 | Clayton | |
| | | US- 3,927,325 | 12-16-1975 | Hungate, et al. | |

FOREIGN PATENT DOCUMENTS

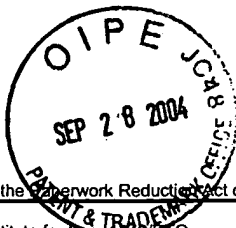
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|--------------------|-----------------------|---|--------------------------------|--|---|----------------|
| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | | CA 1197631 | 12-03-1985 | Leung, et al. | | |
| | | DE 1 065 989 | 09-24-1959 | Rusch K. G. | | |
| | | DE 1 466 774 | 06-04-1969 | Buchler & Co. | | |
| | | DE 3620123 | 12-17-1987 | Vasold, et al. | | |
| | | DE 3 643 893 A1 | 06-30-1988 | Buchler GmbH | | |
| | | DE 3739749A1 | 06-08-1989 | Schreier | | |

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|-----------------------|--------------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | | US- 4,096,862 | 06-27-1978 | DeLuca | |
| | | US- 4,202,323 | 05-13-1980 | Zweig, et al. | |
| | | US- 4,233,517 | 11-11-1980 | van't Hooft | |
| | | US- 4,250,887 | 02-17-1981 | Dardik, et al. | |
| | | US- 4,292,960 | 10-06-1981 | Paglione | |
| | | US- 4,323,055 | 04-06-1982 | Kubiatowicz | |
| | | US- 4,385,635 | 05-31-1983 | Ruiz | |
| | | US- 4,434,788 | 03-06-1984 | Nakatsugawa | |
| | | US- 4,562,001 | 12-31-1985 | Vietzke, et al. | |
| | | US- 4,578,061 | 03-25-1986 | Lemelson | |
| | | US- 4,584,991 | 04-29-1986 | Tokita, et al. | |
| | | US- 4,588,395 | 05-13-1986 | Lemelson | |
| | | US- 4,601,699 | 07-22-1986 | Crain | |
| | | US- 4,654,171 | 03-31-1987 | Boneoeur, et al. | |
| | | US- 4,655,746 | 04-07-1987 | Daniels, et al. | |
| | | US- 4,669,463 | 06-02-1987 | McConnell | |
| | | US- 4,676,258 | 06-30-1987 | Inokuchi, et al. | |
| | | US- 4,697,575 | 10-06-1987 | Horowitz | |
| | | US- 4,702,228 | 10-27-1987 | Russell, Jr., et al. | |

FOREIGN PATENT DOCUMENTS

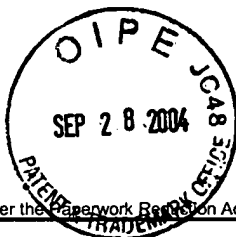
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| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| | | DE 91 02 312.2 U1 | 08-06-1992 | Weigl, et al. | | |
| | | EP 0 152 124 | 08-21-1985 | van't Hooft | | |
| | | EP 0 433 011 A1 | 06-19-1991 | Fischell et al. | | |
| | | EP 0 433 011 B1 | 06-19-1991 | Fischell et al. | | |
| | | EP 0 448 004 A2 | 08-25-1991 | Weigl, et al. | | |
| | | EP 0 448 004 A3 | 08-25-1991 | Weigl, et al. | | |

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|-----------------------|--------------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | | US- 4,706,652 | 11-17-1987 | Horowitz | |
| | | US- 4,726,916 | 02-23-1988 | Aubert, et al. | |
| | | US- 4,733,665 | 03-29-1988 | Palmaz | |
| | | US- 4,762,129 | 08-09-1988 | Bonzel | |
| | | US- 4,763,642 | 08-16-1988 | Horowitz | |
| | | US- 4,763,671 | 08-16-1988 | Goffinet | |
| | | US- 4,768,507 | 09-06-1988 | Fischell, et al. | |
| | | US- 4,770,653 | 09-13-1988 | Shturman | |
| | | US- 4,784,116 | 11-15-1988 | Russell, Jr., et al. | |
| | | US- 4,815,449 | 03-28-1989 | Horowitz | |
| | | US- 4,819,618 | 04-11-1989 | Liprie | |
| | | US- 4,842,590 | 06-27-1989 | Tanabe, et al. | |
| | | US- 4,851,694 | 07-25-1989 | Rague, et al. | |
| | | US- 4,861,520 | 08-29-1989 | van't Hooft, et al. | |
| | | US- 4,878,492 | 11-07-1989 | Sinofsky, et al. | |
| | | US- 4,881,937 | 11-21-1989 | van't Hooft, et al. | |
| | | US- 4,891,165 | 01-02-1990 | Suthanthiran | |
| | | US- 4,897,076 | 01-30-1990 | Puthawala, et al. | |
| | | US- 4,946,435 | 08-07-1990 | Suthanthiran, et al. | |

FOREIGN PATENT DOCUMENTS

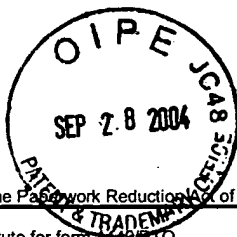
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| | | Country Code ³ -Number ⁴ -Kind Code ⁵ (if known) | | | | |
| | | EP 0 447 745 A2 | 09-25-1991 | Fritz | | |
| | | EP 0 497 495 A2 | 08-05-1992 | Roubin, et al. | | |
| | | EP 0 497 495 A3 | 08-05-1992 | Roubin, et al. | | |
| | | EP 0 593 136 A1 | 04-20-1994 | Fischell et al. | | |
| | | EP 0 688 580 A1 | 12-27-1995 | Verin, et al. | | |
| | | EP 0 829 271 A2 | 03-18-1998 | Liprie | | |

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|--------------------|-----------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | | US- 4,994,013 | 02-19-1991 | Suthanthiran, et al. | |
| | | US- 5,019,075 | 05-28-1991 | Spears, et al. | |
| | | US- 5,030,194 | 07-09-1991 | van't Hooft | |
| | | US- 5,040,548 | 08-20-1991 | Yock | |
| | | US- 5,053,033 | 10-01-1991 | Clarke | |
| | | US- 5,059,166 | 10-22-1991 | Fischell, et al. | |
| | | US- 5,084,002 | 01-28-1992 | Liprie | |
| | | US- 5,103,395 | 04-07-1992 | Spako, et al. | |
| | | US- 5,106,360 | 04-21-1992 | Ishiwara, et al. | |
| | | US- 5,116,864 | 05-26-1992 | March, et al. | |
| | | US- 5,120,973 | 06-09-1992 | Rohe, et al. | |
| | | US- 5,141,487 | 08-25-1992 | Liprie | |
| | | US- 5,147,282 | 09-15-1992 | Kan | |
| | | US- 5,183,455 | 02-02-1993 | Hayman, et al. | |
| | | US- 5,199,939 | 04-16-1993 | Dake, et al. | |
| | | US- 5,209,730 | 05-11-1993 | Sullivan | |
| | | US- 5,213,561 | 05-25-1993 | Weinstein, et al. | |
| | | US- 5,224,933 | 07-06-1993 | Bromander | |
| | | US- 5,267,960 | 12-07-1993 | Hayman, et al. | |

FOREIGN PATENT DOCUMENTS

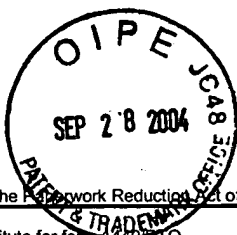
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| | | GB 793,158 | 04-09-1958 | Rummert | | |
| | | GB 1 219 604 A | 01-20-1971 | Nuclesa-Nuclear | | |
| | | GB 1 308 041 A | 02-21-1973 | Jones, et al. | | |
| | | GB 1 558 127 A | 12-19-1979 | van't Hooft | | |
| | | JP 58-78654 | 03-09-1982 | Oximetrix | | |
| | | WO 90/03827 | 04-19-1990 | Hayman, et al. | | |

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| | | US- 5,282,781 | 02-01-1994 | Liprie | |
| | | US- 5,302,168 | 04-12-1994 | Hess | |
| | | US- 5,304,228 | 04-19-1994 | Prince | |
| | | US- 5,306,244 | 04-26-1994 | Shiber | |
| | | US- 5,322,499 | 06-21-1994 | Liprie | |
| | | US- 5,327,885 | 07-12-1994 | Griffith | |
| | | US- 5,342,283 | 08-30-1994 | Good | |
| | | US- 5,354,257 | 10-11-1994 | Roubin, et al. | |
| | | US- 5,354,774 | 10-11-1994 | Deckelbaum, et al. | |
| | | US- 5,395,300 | 03-07-1995 | Liprie | |
| | | US- 5,405,309 | 04-11-1995 | Carden, Jr. | |
| | | US- 5,411,466 | 05-02-1995 | Hess | |
| | | US- 5,417,653 | 05-23-1995 | Sahota, et al. | |
| | | US- 5,460,592 | 10-24-1995 | Langton, et al. | |
| | | US- 5,474,531 | 12-12-1995 | Carter | |
| | | US- 5,476,472 | 12-19-1995 | Dormandy, Jr., et al | |
| | | US- 5,484,384 | 01-16-1996 | Fearnot | |
| | | US- 5,498,227 | 03-12-1996 | Mawad | |
| | | US- 5,503,613 | 04-02-1996 | Weinberger | |

FOREIGN PATENT DOCUMENTS

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| | | Country Code ³ Number ⁴ Kind Code ⁵ (if known) | | | | |
| | | WO 93/04735 | 03-18-1993 | Shefer, et al. | | |
| | | WO 96/11303 A | 05-09-1996 | Novoste Corp. | | |
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| Application Number | 09/468,496 |
| Filing Date | December 21, 1999 |
| First Named Inventor | Ron Waksman et al. |
| Art Unit | 3763 |
| Examiner Name | M. Desanto |
| Attorney Docket Number | WELD 111 DIV IV |

U. S. PATENT DOCUMENTS

| Examiner Initials* | Cite No. ¹ | Document Number | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
|--------------------|-----------------------|--|--------------------------------|--|---|
| | | Number-Kind Code ² (if known) | | | |
| | | US- 5,503,614 | 04-02-1996 | Liprie | |
| | | US- 5,533,969 | 07-09-1996 | Mulder | |
| | | US- 5,556,389 | 09-17-1996 | Liprie | |
| | | US- 5,575,749 | 11-19-1996 | Liprie | |
| | | US- 5,624,372 | 04-29-1997 | Liprie | |
| | | US- 5,643,171 | 07-01-1997 | Bradshaw, et al. | |
| | | US- 5,713,828 | 02-03-1998 | Coniglione | |
| | | US- 5,807,231 | 09-15-1998 | Liprie | |
| | | US- 5,840,064 | 11-24-1998 | Liprie | |
| | | US- 5,851,172 | 12-22-1998 | Bueche, et al. | |
| | | US- 5,857,956 | 01-12-1999 | Liprie | |
| | | US- 5,863,284 | 01-26-1999 | Klein | |
| | | US- 5,899,882 | 05-04-1999 | Waksman, et al. | |
| | | US- 6,013,020 | 01-11-2000 | Meloul, et al. | |
| | | US- 6,074,338 | 06-13-2000 | Popowski, et al. | |
| | | US- 6,306,074 | 10-23-2001 | Waksman, et al. | |
| | | US- 6,458,070 | 10-01-2002 | Waksman, et al. | |
| | | US- 6,503,185 | 01-07-2003 | Waksman, et al. | |
| | | US- 6,514,193 | 02-04-2003 | Kaplan | |

FOREIGN PATENT DOCUMENTS

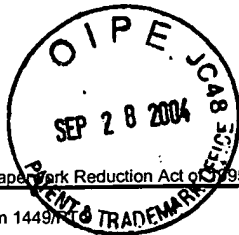
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Application Number

09/468,496

Filing Date

December 21, 1999

First Named Inventor

Ron Waksman et al.

Art Unit

3763

Examiner Name

M. Desanto

Attorney Docket Number

WELD 111 DIV IV

NON PATENT LITERATURE DOCUMENTS

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|-----------------------|--------------------------|---|----------------|
| | 1 | NISAR SYED A.M., FEDER B., "Technique of After-Loading Interstitial Implants", Syed/Feder, Radiologia Clinica 46:458-476 (1977). | |
| | 2 | NISAR SYED et al., "Combination of External and Interstitial Irradiation in the Primary Management of Breast Carcinoma", CANCER vol. 46, No. 6, pp. 1360-1365 (1980). | |
| | 3 | PUTHAWALA et al., "Temporary Iridium 192 Implant in the Management of Carcinoma of the Prostate", ENDOCURIETHERAPY/HYPERTHERMIA ONCOLOGY 1:25-34 (1985). | |
| | 4 | NISAR SYED et al., "Transperineal Interstitial-Intracavitary "Syed-Neblett" Applicator in the Treatment of Carcinoma of the Uterine Cervix", ENDOCURIETHERAPY/HYPERTHERMIA ONC- | |
| | | LOGY 2:1-13 (1985). | |
| | 5 | NISAR SYED A.M. et al., "Intraluminal Irradiation in the Treatment of Esophageal Cancer", ENDOCURIETHERAPY/HYPERTHERMIA ONCOLOGY 3:105-113 (1987). | |
| | 6 | FAXON et al., "Mechanism of Angioplasty and Its Relation to Restenosis", AMERICAN JOURNAL OF CARDIOLOGY 15:5B-9B (1987). | |
| | 7 | BOROK et al. "Rule of Ionizing Irradiation for 393 Keloids", I.J. RADIATION ONCOLOGY-BIOLOGY-PHYSICS 17:77-80 (1989). | |
| | 8 | KOVALIC/PEREZ, "Radiation Therapy Following Keloidectomy: A 20-Year Experience", I.J. RADIATION ONCOLOGY-BIOLOGY-PHYSICS 17:77-80 (1989). | |
| | 9 | MCCORMICK et al., "Breast Cancer", Chpt. 25 of INTERSTITIAL BRACHYTHERAPY 221-226 (1990). | |

Examiner
Signature

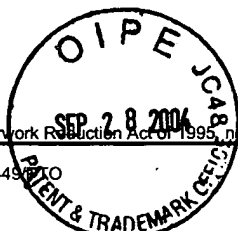
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| Filing Date | December 21, 1999 |
| First Named Inventor | Ron Waksman et al. |
| Art Unit | 3763 |
| Examiner Name | M. Desanto |
| Attorney Docket Number | WELD 111 DIV IV |

Sheet 8

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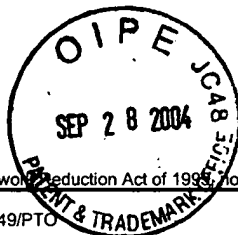
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|--------------------|-----------------------|---|----------------|
| | 10 | DAWSON, "Theoretic Considerations Regarding Low-Dose Radiation Therapy for Prevention of Restenosis after Angioplasty", THE READING HOSPITAL & MEDICAL CENTER 18(1) 4-7 (1991). | |
| | 11 | Skin, p. 261 of the American Medical Association Family Medical Guide, Editor Kunz. | |
| | 12 | Endovascular Low-Dose Irradiation Inhibits Neointima Formation after Coronary Artery Balloon Injury in Swine - A Possible Role for Radiation Therapy in Restenosis Prevention, | |
| | | by Ron WAKSMAN, MD; Keith A. ROBINSON, PhD; Ian R. CROCKER, MD; Michael B. GRAVANIS, MD; Gustavo D. CIPOLLA, DVM; Spencer B. KING III, MD, CIRCULATION vol. 91, No. 5, pp. 1533 | |
| | | -1539 (Mar. 1, 1995). Submitted for publication Oct. 3, 1994. | |
| | 13 | Endovascular Low-Dose Irradiation Inhibits Neointima Formation after Coronary Artery Balloon Injury in Swine - A Possible Role for Radiation Therapy in Restenosis Prevention, | |
| | | by Ron WAKSMAN, MD; Keith A. ROBINSON, PhD; Ian R. CROCKER, MD; Gustavo D. CIPOLLA, DVM; Spencer B. KING III, MD. Submitted for publication Mar. 25, 1994. | |
| | 14 | SCHWARTZ et al., "Effect of External Beam Irradiation on Neointimal Hyperplasia after Experimental Coronary Artery Injury", American College of Cardiology, JACC vol. 19, | |
| | | No. 5, (Apr. 1992), pp. 1106-1113. | |
| | 15 | STEIDLE, B., "Preventative Percutaneous Radiation Therapy to Avoid Hyperplasia of the Intima after Angioplasty Combined with Stent Implantation", STRAHLENTHER ONKOL, (1994), | |

Examiner
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Considered

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| First Named Inventor | Ron Waksman et al. |
| Art Unit | 3763 |
| Examiner Name | M. Desanto |
| Attorney Docket Number | WELD 111 DIV IV |

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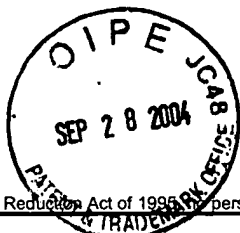
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|--------------------|-----------------------|---|----------------|
| | | 170:151-154. | |
| | 16 | WIEDERMANN et al., "Effects of High-Dose Intracoronary Irradiation on Vasomotor Function and Smooth Muscle Histopathology", AMERICAN PHYSIOLOGICAL SOCIETY, (1994), pp. H125- | |
| | | H132. | |
| | 17 | ABBAS et al., "External Beam Irradiation Inhibits Neointimal Hyperplasia Following Balloon Angioplasty", INTERNATIONAL JOURNAL OF CARDIOLOGY, 44 (1994), 191-202. | |
| | 18 | LIERMANN et al., "Interventional Treatment and Clinics in Combination with Prophylactic Endovascular Radiation in the Therapy of Intimal Hyperplasia", RADIOLOGE, (1994) 34, | |
| | | 524-533. | |
| | 19 | SHIMOTAKAHAR and MAYBERG, "Gamma Irradiation Inhibits Neointimal Hyperplasia in Rats after Arterial Injury", STROKE, vol. 25, No. 2, pp. 424-428, (Feb. 1994). | |
| | 20 | WIEDERMANN et al., "Intracoronary Irradiation Markedly Reduces Restenosis after Balloon Angioplasty in a Porcine Model", American College of Cardiology, JACC, vol. 23, No. 6, | |
| | | pp. 1491-1498 (May 1994). | |
| | 21 | FISCHELL et al., "Low-Dose, Beta-Particle Emission from 'Stent' Wire Results in Complete, Localized Inhibition of Smooth Muscle Cell Proliferation", BASIC SCIENCE REPORTS, | |

Examiner
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Considered

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|-----------------------|--------------------------|---|----------------|
| | | Circulation, vol. 90, No. 6, (Dec. 1994), pp. 2956-2963. | |
| | 22 | FRIEDMAN, "Pathogenesis of the Spontaneous Atherosclerotic Plaque", ARCHIVES OF PATHOLOGY, vol. 76, (Sept. 1963), 94-105. | |
| | 23 | FRIEDMAN et al., "Cortisone and Experimental Atherosclerosis", ARCHIVES OF PATHOLOGY, vol. 77, (Feb. 1964), 56-72. | |
| | 24 | FRIEDMAN et al., "Aortic Atherosclerosis Intensification in Rabbits by Prior Endothelial Denudation", ARCHIVES OF PATHOLOGY, vol. 79, (Apr. 1965), 345-356. | |
| | 25 | FRIEDMAN and BYERS, "Effect of Iridium 192 Radiation on Thromboatherosclerotic Plaque in the Rabbit Aorta", ARCHIVES OF PATHOLOGY, vol. 80, (Sep. 1965). | |
| | 26 | FRIEDMAN, FELTON, and BYERS, "The Antiatherogenic Effect of Iridium 192 upon the Cholesterol-fed Rabbit", Journal OF CLINICAL INVESTIGATION, vol. 43, No. 2, (1964), 185-192. | |
| | 27 | HILARIS, B.S., et al., ATLAS OF BRACHYTHERAPY Chapter 2, "Brachytherapy Instruments", title & cover pages, p. 28, pp. 42-43, (1988). | |
| | 28 | MELKERT, R., et al., "Luminal Narrowing after Percutaneous Transluminal Coronary Angioplasty. A Multivariate Analysis of Clinical, Procedural and Lesion Related Factors Affecting Long-term Angiographic Outcome in the PARK Study", J. INVASIVE CARDIOLOGY, vol. 6, No. 5, pp. 160-171 (Jun. 1994). | |
| | 29 | FISHMAN, D., et al., Abstract: "A Randomized Comparison of Coronary-stent Placement and Balloon Angioplasty in the Treatment of Coronary Artery Disease", NEW ENGLAND J. OF | |

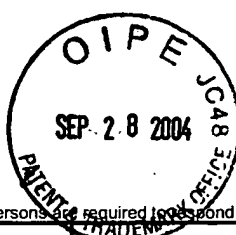
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|--------------------|-----------------------|---|----------------|
| | | MEDICINE, p. 496 (Aug. 25, 1994). | |
| | 30 | NICOLINI, F., et al., "Biology of Restenosis and Therapeutic Approach", ENDOVASCULAR SURGERY, vol. 72, No. 4, pp. 919-935 (Aug. 1992). | |
| | 31 | WEIDERMANN, J., et al., Abstract: "Intracoronary Irradiation Acutely Impairs Endothelial and Smooth Muscle Function as Assessed by Intravascular Ultrasound", Supplement to | |
| | | CIRCULATION, vol. 86, No. 4, p. I-188, Abstract No. 0750 (Oct. 1992). | |
| | 32 | LANDAU, C., et al., "Percutaneous Transluminal Coronary Angioplasty", NEW ENGLAND J. OF MED., vol. 3330, No. 14, pp. 981-983 (Apr. 7, 1994). | |
| | 33 | PARANANDI, S., et al., "Contemporary Clinical Trials of Restenosis", J. OF INVASIVE CARDIOLOGY, vol. 6, No. 4, pp. 109-123 (May 1994). | |
| | 34 | WIEDERMANN et al., "Intracoronary Irradiation Markedly Reduces Restenosis after Balloon Angioplasty in a Porcine Model", JACC, vol. 23, No. 6, pp. 1491-1498 (May 1994). | |
| | 35 | GLAGOV, S., "Intimal Hyperplasia, Vascular Modeling, and the Restenosis Problem", CIRCULATION, vol. 89, No. 6, pp. 2888-2891 (Jun. 1994). | |
| | 36 | BOTTCHEr et al., "Endovascular Irradiation - A New Method to Avoid Recurrent Stenosis after Stent Implantation in Peripheral Arteries: Technique and Preliminary Results", I.J. | |
| | | RADIATION ONCOLOGY, BIOLOGY, PHYSICS, vol. 29, (Nov. 1994), 183-186. | |

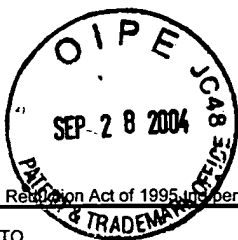
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STATEMENT BY APPLICANT**

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| | |
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| Application Number | 09/468,496 |
| Filing Date | December 21, 1999 |
| First Named Inventor | Ron Waksman et al. |
| Art Unit | 3763 |
| Examiner Name | M. Desanto |
| Attorney Docket Number | WELD 111 DIV IV |

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NON PATENT LITERATURE DOCUMENTS

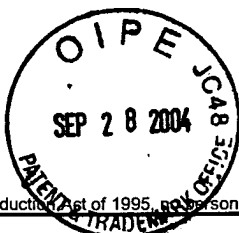
| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|--------------------|-----------------------|---|----------------|
| | 37 | LIERMANN et al. "Prophylactic Endovascular Radiotherapy to Prevent Intimal Hyperplasia after Stent Implantation in Femoropopliteal Arteries", CARDIOVASCULAR AND INTERVENTIONAL RADIOLOGY, (1994), 17:12-16. | |
| | 38 | Supplementary European Search Report - EP 97 92 2288. | |
| | 39 | Annex to the European Search Report on European Patent Application No. EP 97 92 2288. | |
| | 40 | HERRMAN, J., et al., "Pharmacological Approaches to the Prevention of Restenosis Following Angioplasty", DRUGS, 46(1): pp. 18-52 (1993). | |
| | 41 | LANGE, R., et al., "Southwestern Internal Medicine Conference: Restenosis: The Achilles Heel of Coronary Angioplasty", AMER. J. OF THE MEDICAL SCIENCES, vol. 306, pp. 265-273 (Oct. 1993) | |
| | 42 | MYLER, R., et al., "Restenosis after Coronary Angioplasty: Pathophysiology and Therapeutic Implications (Part 1 of Two Parts), J. OF INVASIVE CARDIOLOGY, vol. 5, No. 8, pp. 278-285, (Oct. 1993). | |
| | 43 | WEIDERMAN, J., et al., Abstract: "Intracoronary Irradiation Markedly Reduces Restenosis after Balloon Angioplasty in a Porcine Model", Supplement of CIRCULATION, vol. 88, | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

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| Examiner Initials* | Cite No. ¹ | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-----------------------|--------------------------|---|----------------|
| | | No. 4, pt. 2, p. I-655, Abstract No. 3529 (Oct. 1993). | |
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